

RECEIVED  
CENTRAL FAX CENTER

JAN 05 2007

REMARKS

Claims 1 - 42 and 47 - 60 have been withdrawn from consideration. Claims 43 - 46 and 61 remain pending in this application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 43 and 44 stand rejected under 35 U.S.C. § 102(b) as anticipated by Yoon (U.S. Patent No. 5,797,888).

Claim 43 recites a device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.*"

The Examiner stated that the arguments previously advanced were persuasive with respect to claim 61 but not with respect to claim 43. The Examiner stated that claim 43 is broader -- "the valve flaps open out whether due to a force of a solid object or the force of a differential fluid pressure." Applicants fail to understand the distinction the Examiner is making as claim 43 specifically recites a compound slit "*opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.*"

As stated previously, Yoon describes a cannula 20 for insertion through an anatomical cavity wall including a tubular body 22 with a valve 26 at a proximal end thereof which opens *only* when a trocar 36 is thrust therethrough. (See *id.*, col. 4, lines 18-20). The valve 26 includes four flaps (valve members) 28-34 biased toward a closed position "when no instrument is passed through the cannula." (See *id.*, col. 4, lines 1-3). The flaps 28-34 open outwardly *only* when the trocar 36 is pushed therethrough. (See *id.*, col. 4, lines 27-32). The valve of Yoon prevents fluid from passing through the cannula 20 at all times -- i.e., the valve of Yoon seals tight when no trocar 36 is inserted through the cannula 20 and seals around an outer surface of any trocar 36 inserted therethrough. At no point does fluid pressure open this valve.

The Examiner stated that the slit in Yoon would inherently open due to a difference in

pressure between the lumen and the ambient and that the slit of Yoon is configured to allow the flaps "to flex outward when the internal pressure exceeds the internal pressure by a second amount." Initially it is noted that a structures such as a watertight bulkhead will also inherently open when subjected to great enough fluid pressures. However, it is respectfully submitted that the opening of the valve of Yoon or a watertight bulkhead due to fluid pressure represents a failure of the structure -- i.e., behavior directly contradicting the purpose for which it was designed. Thus, Applicants respectfully disagree with the Examiner's characterization of the valve of Yoon as "configured" to allow the flaps to open due to a pressure differential. In fact it is configured to precisely the opposite by remaining sealed at all times and at all pressure differentials to which it is expected to be exposed.

Accordingly, it is respectfully submitted that Yoon teaches away from the configuration recited in claim 43 and it is therefore respectfully submitted that Yoon neither illustrates nor describes a device comprising "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter.*" It is therefore respectfully submitted that claim 43 is not anticipated by Yoon and that this rejection should be withdrawn. Because claim 44 depends from and, therefore, includes all of the limitations of claim 43, it is respectfully submitted that this claim is also allowable.

Claims 43, 44 and 61 stand rejected under 35 U.S.C. § 102(b) as anticipated by Eaton (U.S. Patent No. 3,303,847). The Examiner stated, in support of the rejection, that the slit in Eaton is configured to open inwardly when the ambient pressure exceeds the lumen pressure. (See 11/14/06 Office Action, ¶ 5).

It is respectfully submitted that Eaton fails to show a compound slit "biased toward a closed position and *opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter,*" as recited in claim 43. Eaton shows a "collapsible or squeezable tube" which opens only when the body portion 1 is physically deformed by a manual pressure applied thereto and which remains closed at all times when no manual pressure is applied. Specifically, Eaton states that "pressure applied to the body portion 1 will cause the slits or cuts 8 and 9 of the flexible catheter to part slightly. (See *id.*, col. 3, lines 67 - 68). Eaton further states that, "when the container is not subjected to pressure, such [an] opening will remain closed sufficiently tightly to retain the contents of the container-applicator

against the force of gravity.” (See *id.*, col. 3, line 73 - col. 4, line 1).

The Examiner states that the applicant has misunderstood the Eaton reference and that the valve of Eaton opens when the container is squeezed because this increases a fluid pressure within the container. However, it is respectfully submitted that Eaton includes no description or suggestion of this and, in fact, includes no mention of fluid pressure in any way influencing the state of the valve. It is submitted that the direct statement in Eaton that the slits part slightly when the container is squeezed is at least as likely to describe mechanical deformation of the valve due to the squeezing as any pressure activated valve behavior and any suggestion that this is a pressure activated valve is being read into the patent by the Examiner.

Accordingly, it is submitted that Eaton describes a valve which opens only under physically deforming, mechanical pressure and teaches away from a valve opening in response to fluid pressure as recited in claim 43 and that Eaton neither illustrates nor describes a “compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter,*” as recited in claim 43.

Because claims 44 and 61 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are also allowable.

Claims 43, 44, 46 and 61 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ferguson (U.S. Patent No. 2,063,424).

Initially, it is respectfully submitted that Ferguson does not show a catheter as recited in claim 43. A catheter is a tubular device “designed for insertion into canals, vessels, passageways, or body cavities so as to permit injection or withdrawal of fluids or substances or to maintain the openness of a passageway.” (Webster’s Third International Dictionary, 1986). This definition is entirely consistent with the detailed description and figures of the present invention. In contrast, the nipple for a baby’s bottle shown by Ferguson is designed to be grasped between a baby’s lips and is not suitable for the injection to or withdrawal of any substance from a body cavity. Injection is defined as driving or forcing fluid into a vessel, cavity or tissue (*Id.*) while the nipple is simply a device like a straw which allows an infant to draw fluid from a container. In addition, it is submitted that, similar to Eaton, the valve of Ferguson does not open in response

to fluid pressure applied thereto. Rather, the valve of Ferguson is opened by the physical deformation of the nipple as it is squeezed in the mouth of the infant with the suction drawing the liquid through this opening. Specifically, Ferguson states that, during use:

the nipple is of course positioned between the jaws of infant; and obviously, closure of the infant's jaws will compress the nipple from above and below, with the result that the slots will gape in the manner illustrated in Figs. 4 and 5...It will be readily understood, that when the nipple is applied to a bottle containing liquid food; the normal jaw action of the infant in the act of nursing will regulate the size of the orifice and consequently the flow of food.

See id., page 1, col. 2, line 49 to page 2, col. 1, line 17 See id.

The Examiner stated that the slit of Ferguson is biased closed and opens due to differences in pressure between the lumen and the ambient. (See 11/14/06 Office Action, ¶ 6). However, as illustrated by this quoted passage, it is submitted that the nipple of Ferguson opens only when mechanically compressed between the jaws of an infant and does not open due to a pressure differential. Although a pressure differential applied by an infant's sucking may enlarge an opening, the opening is only created by the compression from the infant's jaws. (See id., page 2, col. 1, lines 20 - 23). In addition, Ferguson states that the improved nipple contains perforation 6 and that "no amount of either compression or distortion can possibly close this vent 6." (See id., page 2, col. 2, lines 18-22; Fig. 7). Furthermore, the intersecting slots 3, 4, and 5 are never fully closed and "no amount of compression or distortion can possible close the slots 3, 4, 5." (See id., page 2, col. 2, lines 63 - 65). shows a nipple for a baby bottle which is designed to open through the jaw action of an infant. The nipple of Ferguson is designed to exhibit substantially uniform behavior regardless of its rotational position within an infant's mouth. That is, the nipple of Ferguson opens in substantially similarly despite the orientation of slits therein to the direction of the compressive force from the jaws. Specifically, Ferguson states that, in any position one of the slots "will invariably be within 15 degrees of either vertical position, or horizontal position...and that such slight variations from the direction of compression, will not, to any appreciable extent affect the result of compression illustrated in Figs. 4 and 5. (See id., Col. 2, lines 41 - 48). Thus, it is clear that the opening of the slots shown in Figs. 4 and 5 is the result of the mechanical compression of the nipple due from the jaws and not due to a fluid pressure differential.

Thus, it is respectfully submitted that Ferguson neither illustrates nor describes a device comprising "an elongate catheter including an external surface and at least one internal surface

defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter” and “a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being *biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter,*” as recited in claim 43. It is therefore respectfully submitted that claim 43 is not anticipated by Eaton and that this rejection should be withdrawn. Because claims 44, 46, and 61 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are also allowable.

Claims 43, 44 and 46 stand rejected under 35 U.S.C. § 102(b) as anticipated by Yamauchi (U.S. Patent No. 2,063,429).

Similarly to Ferguson, it is respectfully submitted that Yamanuchi does not show a catheter as recited in claim 43. A catheter is a tubular device “designed for insertion into canals, vessels, passageways, or body cavities so as to permit injection or withdrawal of fluids or substances or to maintain the openness of a passageway.” (Webster’s Third International Dictionary, 1986). Furthermore, similar to Ferguson, the valve of Yamanuchi is subjected to the combination of jaw compression and suction associated with nursing and opens in response to fluid pressure applied thereto. Rather, the valve of Yamanuchi is opened by the physical deformation of the nipple as it is squeezed in the mouth of the infant with the suction drawing the liquid through this opening. It is respectfully submitted that the term “suction” as used in Yamanuchi is used to describe the process by which an infant draws milk from a bottle or breast. However, anyone who has milked a cow or seen that a cow can be milked by hand will realize that the milk is drawn from the breast by a squeezing, pulling action and that such “suction” need not involve the application of any negative air pressure. The same is true of nipples for infant bottles as they are designed to operate in a manner resembling as closely as possible a natural breast.

It is respectfully submitted that mechanical deformation is required to open the nipples of Ferguson and Yamanuchi and that nothing in either of these disclosures teaches or suggests a valve which opens due to the application of negative pressure. Finally, it is submitted that this difference (i.e., the required mechanical deformation provided by an infant’s jaws) underscores the distinction between the nipples of these references and the catheter valve recited in the claims of this application.

It is therefore respectfully submitted that Yamanuchi neither shows nor suggests a device comprising “an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter” and “a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being *biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter,*” as recited in claim 43. It is therefore respectfully submitted that claim 43 is not anticipated by Yamanuchi and that this rejection should be withdrawn. Because claims 44 and 46 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are also allowable.


Claim 45 stands rejected as obvious over Eaton in view of Engelson et al. (U.S. Patent No. 5,789,018) and over Yoon in view of Engelson. The Examiner stated, in support of these rejections, that each of Eaton and Yoon shows the invention substantially as claimed except for the collar but that Engelson shows a collar as claimed.

However, it is respectfully submitted that Engelson does not cure the deficiencies described above with reference to Eaton and Yoon -- i.e., a catheter including “a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, the compound slit being *biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter*” as recited in claim 43 from which claim 45 depends. Thus, it is respectfully submitted that claim 45 is allowable for the same reasons stated above in regard to claim 43.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated: January 5, 2007



Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP  
150 Broadway, Suite 702  
New York, New York 10038  
Tel: (212) 619-6000  
Fax: (212) 619-0276